

**REMARKS**

Reconsideration and withdrawal of the rejections of the application are respectfully requested in view of the remarks herein. The Examiner is thanked for withdrawing the previous art rejections based on Krieg.

**I. STATUS OF THE CLAIMS AND FORMAL MATTERS**

Claims 1, 3-4, 6-17, 20-26, 28-32 and 35-40 and 42-44 are now pending. Claims 20 and 32 have been amended, claim 42 has been canceled, and claim 44 has been added herein, without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents.

No new matter is added.

It is submitted that these claims are and were in full compliance with the requirements of 35 U.S.C §112. In addition, the amendment and remarks herein are not made for the purpose of patentability within the meaning of 35 U.S.C. §§101, 102, 103 or 112; but rather the amendments and remarks herein are made simply for clarification and to round out the scope of protection to which Applicants are entitled. Support for the amended claims is found throughout the specification.

It is noted that Applicants continue to disagree with the priority date assigned this application.

**II. THE OBJECTIONS TO THE CLAIMS ARE OVERCOME**

Claim 43 was also objected to as being a substantial duplicate of claim 42. Claim 42 has been cancelled herein rendering this objection moot. Reconsideration and withdrawal of the objection is respectfully requested.

**III. THE REJECTIONS UNDER 35 U.S.C. §112 ARE OVERCOME**

Claim 32 was rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter of the invention.

Specifically, the Office Action stated that there was no antecedent basis for the recitation of "multiple applications of the delivery device including the vector" in claim 32.

Applicants respectfully submit that the amendments herein have rendered these rejections moot. Accordingly, reconsideration and withdrawal of the rejection of the claim under 35 U.S.C. §112, second paragraph, is respectfully requested.

### **III. THE ART REJECTIONS ARE OVERCOME**

Claims 1, 9-15, 21-23, 26, 28-29, 38 and 42-43 were rejected under 35 U.S.C. §102(e) as allegedly being anticipated by Roop et al. (US 6,143,727). Claims 1, 9-15, 21-23, 26, 28-29, 38 and 42-43 were rejected under 35 U.S.C. §102(e) as allegedly being anticipated by Carson et al. (US 5,679,647). Claims 1, 4, 16-17, 24-25, 30-31, 35-37 and 40 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over either Powell et al. (US 5,877,159) or WO 01/89535 in view of Roop. Claims 1, 29 and 39 were rejected under 35 U.S.C. §103(a) as allegedly unpatentable over either Carson et al. or Roop et al., in view of either Alexander or Li.

Applicants respectfully remind the Examiner that a two-prong inquiry must be satisfied in order for a Section 102 rejection to stand. First, the prior art reference must contain all of the elements of the claimed invention, *see Lewmar Marine Inc. v. Barent Inc.*, 3 U.S.P.Q.2d 1766 (Fed. Cir. 1987), and, the single prior art reference must contain an enabling disclosure, *see Chester v. Miller*, 15 U.S.P.Q.2d 1333, 1336 (Fed. Cir. 1990).

Furthermore, the Examiner respectfully reminded that for a Section 103 rejection to be proper, there must be some prior art teaching which would have provided the necessary incentive or motivation for modifying the reference teachings to arrive at the claimed invention. *In re Laskowski*, 12 U.S.P.Q. 2d 1397, 1399 (Fed. Cir. 1989); *In re Obukowitz*, 27 U.S.P.Q. 2d 1063 (BOPAI 1993). Further, the Examiner is respectfully reminded that “obvious to try” is not the standard under 35 U.S.C. §103. *In re Fine*, 5 U.S.P.Q. 2d 1596, 1599 (Fed. Cir. 1988). And, as stated by the Court in *In re Fritch*, 23 U.S.P.Q. 2d 1780, 1783-1784 (Fed. Cir. 1992): “The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggests the desirability of the modification.” Also, the Examiner is additionally respectfully reminded that for the Section 103 rejection to be proper, **both the suggestion of the claimed invention and the expectation of success must be founded in the prior art, and not Applicants’ disclosure.** *In re Dow*, 5 U.S.P.Q.2d 1529, 1531 (Fed. Cir. 1988).

The Examiner is also respectfully reminded that MPEP 2143.01 mandates that for a Section 103 rejection, there must be some suggestion or motivation to modify reference teachings, and, that MPEP 2143.02 further mandates that for a section 103 rejection, there must be a reasonable expectation of success.

Applicants again submit that both Roop and Carson relate to the administration of plasmid vectors, not "bacterial vectors" as is required by the pending claims. Contrary to the assertions of the Office Action, plasmid vectors do not meet each and every limitation of the claims. Applicants respectfully remind the Examiner that when interpreting the scope of the pending claims, including the term "bacterial vector", the claims must be read in light of the specification and the art as a whole.

One of skill in the art is certainly aware that plasmid vectors are small circular molecules of double stranded DNA derived from natural plasmids that occur in bacterial cells. That is, a plasmid vector is not a bacterial vector, rather, plasmid vectors can exist in bacteria. The term "bacterial vector" as used herein does not refer to a vector taken from within a bacteria, i.e., it does not refer to plasmid vectors that are only a portion of what makes up a bacteria. Rather, the term "bacterial vector" is used to indicate a vector comprising a bacteria, which bacteria can contain and express a nucleic acid molecule encoding a gene product of interest. Indeed, a plasmid vector cannot be considered a bacteria vector as it does not encompass the bacteria itself.

Such a distinction has been recognized previously by the Office. Indeed, Applicants respectfully direct the Examiner's attention to related US Patent No. 6,716,823, which contains claims directed to the use of vectors to induce a systemic immune response. The '823 patent was granted over several references by Carson, attesting to the recognized differences between the cited references and the claimed invention.

Accordingly, as neither Carson nor Roop either teach or suggest the use of bacterial vectors as the term is recognized and used in the art, the rejections based on these references cannot stand. As each and every art rejection provided in the Office Action rely on Roop and/or Carson, Applicants respectfully submit that the rejections must therefore be withdrawn.

Consequently, reconsideration and withdrawal of the rejections under 35 U.S.C. §§ 102(e) and 103(a) are respectfully requested.

**IV. THE DOUBLE PANTENTING REJECTIONS ARE OVERCOME**

Claims 1, 9-15, 21-23, 26, 28-29, 38-39 and 42-43 were rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-3 of U.S. patent No. 6,706,693. Claims 1, 4, 6, 9-17, 20-26, 28-32, 35-40 and 42-43 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-42 of copending Application Serial No. 10/346,021. Applicants will consider these rejections, including the possibility of filing a terminal disclaimer to obviate the rejections, upon the determination of allowable subject matter in the present application.

And, claims 1, 11-13, 25, 28-29 and 38-39 were provisionally rejected under 35 U.S.C. §101 as claiming the same invention as that of claims 1, 6-8, 20, 23-24 and 33-34 of copending Application Serial No. 10/116,963. Applicants believe that the elections of species between the applications will result the avoidance of this rejection upon the determination of allowable subject matter. Accordingly, this rejection will be considered at such time as the pending claims have otherwise been deemed allowable.

**REQUEST FOR INTERVIEW**

If any issue remains as an impediment to allowance, prior to issuance of any paper other than a Notice of Allowance, an interview, is respectfully requested, with the Examiner and his supervisor, and, the Examiner is respectfully requested to contact the undersigned to arrange a mutually convenient time and manner for such an interview.

**CONCLUSION**

In view of the amendments, and remarks herein, the application is in condition for allowance. Reconsideration and withdrawal of the rejections of the application, and prompt issuance of a Notice of Allowance, is respectfully requested.

Respectfully submitted,

FROMMER LAWRENCE & HAUG LLP

By: /Angela M. Collison/  
Thomas J. Kowalski  
Reg. No. 32,147  
Angela M. Collison  
Reg. No. 51,107  
(212) 588-0800